37

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,902	10/01/2003	Kirk Matthew Schnorr	10274.200-US	8351

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EXAMINER	
GEBREYESUS, KAGNEW H	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,902	SCHNORR ET AL.	
	Examiner	Art Unit	
	Kagnew H. Gebreyesus	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response on January, 6, 2006 to the Office Action mailed on July 6, 2005 is acknowledged. Claims 40-59 have been cancelled. Claims 60-87 have been added and are present for consideration.

Claim Objections

Claims 67-73 are objected to because of the following informalities: Claims 67-73 depend on claim 46, a claim that has been cancelled. Appropriate correction is required. For examination purposes claims 67-73 depend on claim 66.

Withdrawn – Objection to the specification

The objection to the specification is withdrawn following the correction of typographical error.

Withdrawn –Claim Objection

The objection to claims 40-59 have been withdrawn following the amendment to the independent claims reciting glycoside hydrolase.

Maintained - Claim Rejections - 35 USC § 112

1. Claims 60-73 (corresponding to previous claims 40-54) remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue: "Claims 40-53 are drawn to methods of preparing an edible products using a GH-61 polypeptide. Applicants have shown in the specification that these polypeptides retard the staling of edible products. Thus, these claims are drawn to a new use of a class of enzymes. This is a pioneering invention, and therefore Applicants are entitled to broad claims for this invention. For the foregoing reasons, Applicants submit; that the claims overcome this rejection under 35 U.S.C. 112."

However this argument is not found persuasive for the following reasons. The specification relies upon the definition of the CAZY GH classification system to define the glycoside hydrolase polypeptide, GH-61. This definition relies on conserved sequence portions and folding of GH proteins. However functional variations of GH polypeptides clearly exists within a members of the same family of GH proteins. For instance, as many as 21 different reactions and product specificities such as α-amylase I activity, isoamylase activity, branching-enzyme activity, sucrose phosphorylase activity and etc are found in different members of the α-amylase/ GH-13 family. Within the α-amylases, maltogenic amylases have been used as anti-staling agents to prevent the retrogradation of starch in bakery products (See Marc J.E.C van der Maarel in Journal of Biotechnology 94 (2002) 137-155). Furthermore, most of the GH-61 family polypeptides isolated from various organisms have not been functionally defined and enzyme classification numbers (E.C number) have not been assigned.

Therefore although GH-61 polypeptides may belong in the same family of proteins, the function of all of these proteins has not been elucidated and members of this family are also expected to catalyze many different reactions and may have different product specificities or. Applicants have disclosed specific polypeptide sequence of SEQ ID NO: 2, SEQ ID NO: 4 and SEQ ID NO: 6 however applicants have not described any other representative species by any identifying characteristics or properties other than being a member of a GH-61 family.

Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention i.e. all known and unknown GH-61 polypeptide from any source that possess anti-staling activity.

Claims 60-75, 78, 81 and 86 (corresponding to previous claims40-57) remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptides of SEQ ID NO: 2, 4 and 6 and the method using the same to prevent staling of edible products, does not reasonably provide enablement for any GH-61 from any source (as encompasses by claims 60-73 (corresponding to previous claims 40-53)) or any GH-61 polypeptide having 90-95% identity to an enzyme of SEQ ID NO: 2 or 4 (now encompassed by claims 74-76, 78-79, 81-82, 84, 86 and 87) and method of use thereof to prevent staling. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants argue: "Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of section 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support" In re Marzocchi, 169 USPQ at 369.

Furthermore applicants argue: "It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed. In re Dinh-Nguyenb181 O.S.P.Q. 46 (C.C.P.A, 1974). See also U.S. F: Telectronics, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988: In re Bowen, 181 U.S.P.Q. 48 (C.C.P.A. 1974); Ex parte Hitzeman. 9 U.S.P.Q.Zd 1821 (BPAI 1988). Moreover, in the absence of any evidence or apparent reason why compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. In re Kamal, 158 U.S.P.Q. 320 (C.C.P.A. 1968). See also In re

Stark, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972) (the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter)".

Applicant's argument has been carefully considered but not found persuasive. Although the specification in examples 9, tables 1-3 show the effect of SEQ ID NOS: 2, 4 and 6 on quality of baked bread including, firmness during storage, Table 1, elasticity during storage Table 2 and water mobility in Table 3, as explained in the rejection above, the function of all GH-61 family member proteins have not been elucidated and individual members of this family can catalyze many different reactions and have different product specificities. Therefore without the knowledge of the reactions that can be catalyzed or the product specificity of all GH-61 polypeptides, the specification does not enable the enormous scope encompassed by the claims.

Applicants further argue: "We draw the Examiner's attention to *In re Angstadt* 190 USPQ 214 (CCPA 1976). *In re Angstadt* the claimed process of preparing hydroperoxides used a metal salt complex as a catalyst. The specification disclosed catalysts that worked and some that gave little or no yield of hydroperoxides. The claims were rejected for lack of enablement, specifically as requiring undue experimentation to find useful catalysts. This rejection was reversed by the CGPA..."

However claims 60-73 are drawn to a method of using any GH-61 from any source or any GH-61 polypeptide (claim 74) to prepare an edible product. In addition sequences of GH-61 having 90% identity to an enzyme of SEQ ID NO: 2 or 4 or 6 are also encompassed (claims 74, 75, 78, 81) are encompassed. The scope of the claims is not commensurate with the enablement provided by the disclosure because the function of all GH-61 family member proteins have not been elucidated while other members of this family are known to catalyze many different reactions and have different product specificities. Thus the patent protection sought with regard

to the enormous number of characterized and uncharacterized glycoside hydrolase enzymes broadly encompassed by the claims have not been enabled.

In *In re Angstadt* et al applicants have disclosed forty examples with or without activities. Applicants claims encompassing a method of using all GH-61 proteins from any source or polypeptides showing 90% identity to SEQ ID NO: 2, 4 or 6 and having anti-staling activity is not supported by the specification. In order to enable such a recitation applicants would have to affirm that all members of the GH-61 family polypeptides are capable of anti-staling activity. Given that the claims are drawn to a method of using rather than screening for a GH-61 polypeptide that can be used as an anti-staling agent, as claimed one will require to first isolate any GH-61 family polypeptides from any source, identify a sub-class thereof with a common structural feature required for anti-staling activity in order to enable the enormous scope encompassed by the claims. In addition polypeptides in other family members such as GH-13 family are known to have polypeptides with anti-staling activity therefore being a GH-61 member polypeptide does not limit the claims by a structure/function correlation. Thus the specification does not provide enablement for any GH-61 from any source encompassed by claims 60-73 or any GH-61 polypeptide having 90-95% identity to an enzyme of SEQ ID NO: 2, 4 or 6 by claims 74-76, 78, 79, 81, 82, 84, 86 and 87 and method of use thereof to prevent staling. For this reason the rejection under 35 U.S.C. 112, first paragraph is maintained.

Withdrawn - Claim Rejections - 35 USC § 112

Claim 54 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection has been withdrawn following the cancellation of claim 54.

Claim Rejections - 35 USC § 102

2. Claims 40-54 (corresponding to claims 60-73) were rejected under 35 U.S.C. 102(b) as being anticipated by Saloheimo et al, (1997) et al. Saloheimo et al, disclose a glycoside hydrolase family 61 polypeptide wherein the nucleotide sequence and encoded polypeptide sequence were submitted to GenBank with the accession no. Y11113.

Furthermore Claims 40-54 (corresponding to claims 60-73) were rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al, (2001).

Applicants argue: "The Saloheimo et al. reference is said to disclose a GH-61 polypeptide. However, Saloheimo et al. do not disclose dough compositions comprising or methods for preparing an edible product using a GH-61 polypeptide, as claimed in claims 60-73. Moreover, Saloheimo et al. do not disclose the polypeptide claimed in 74-87, namely polypeptides having an amino add sequence which has at least 90% identity to amino acids 1-216 of SEQ ID NO: 2, amino acids 1-304 of SEQ ID NO: 4, or amino acids 1-201 of SEQ ID NO: 6, or which are encoded by a nucleotide sequence which hybridizes under medium stringency conditions with any of the polynucleotides probes recited in claim 74".

Applicant's argument has been considered and have been found partially persuasive i.e. the rejection of claims 60-65 has been withdrawn, however claims 66-73 remain rejected under 35 U.S.C. 102(b) as being anticipated by Saloheimo et al, (1997) and under Ito et al, (2001) because unlike the method of claims 60-65, the composition comprising a new product is still drawn to the

product and the claims are not drawn to any method therefor the subject of patentability as claimed is drawn to a product.

Claim Objections

Claims 76, 77, 79, 80, 82-85 and 87 are objected to for depending on rejected claims however will be allowable if re-written in independent form.

Relevant patents and publications:

1. US PAT 5,610,048
2. US PAT 6365204 B1
3. Properties and applications of the starch converting enzymes of the α-amylase family. Marc J.E.C van der Maarel in Journal of Biotechnology 94 (2002) 137-155).
4. Improvement of the bread making quality of wheat flour by the hyperthermophylic xylanase B from Thermotoga maritima. Zhengqiang et al. Food research international 38 (2005) 37-43.

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment complying with the requirements set forth below.

If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

Kagnew Gebreyesus PhD.

REBECCA E. PRUITT
PRIMARY EXAMINER
GROUP ~~1800~~ 1600